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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' MOTION AND
MEMORANDUM IN SUPPORT FOR
SUMMARY JUDGMENT AS TO
PLAINTIFFS DEBRA AND JAMES
FRANCES TINLIN'S CLAIMS**

(Assigned to the Honorable David G.
Campbell)

(Oral Argument Requested)

MOTION

Pursuant to Fed. R. Civ. P. 56, Local Rule 56.1, and Case Management Order No. 39 (Doc. 12971), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively “Bard”) respectfully move this Court for summary judgment as to certain of the plaintiffs’ product liability claims (Counts II, III, VII, VIII, XII, XIII, XIV, and XV) as alleged in the plaintiffs’ Short Form Complaint (2:16-cv-00263-DGC, Doc. 1). The plaintiffs have agreed to withdraw their remaining claims for manufacturing-related issues (Counts I,V), negligent failure to recall/retrofit (Count VI), negligence per se (Count IX), breach of express warranty (Count X), and breach of implied warranty (Count XI). Thus, if Bard’s Motion is granted in full, then all of the plaintiffs’ claims will be resolved without the need for trial.

This Motion is supported by Defendants’ Memorandum of Points and Authorities and Separate Statement of Facts (“SOF”) which are filed herewith.

MEMORANDUM OF POINTS AND AUTHORITIES**I. Introduction.**

This case concerns a rare complication of a Recovery Filter: fracture of the filter resulting in open heart surgery. Plaintiff, Debra Tinlin, is an obese, wheelchair-dependent 54-year-old woman with many significant medical conditions, including severe neurologic disorder, spinal degeneration, asthma, diabetes, high blood pressure, high cholesterol, and hyperthyroidism. In 2005, Mrs. Tinlin suffered a life-threatening, bilateral pulmonary embolism despite treatment with anticoagulation. To protect Mrs. Tinlin against another and potentially fatal pulmonary embolism, her doctor wanted to place a retrievable filter, the Recovery Filter, until her doctors could develop a long-term course of treatment concerning her potential blood clotting disorder. Mrs. Tinlin never experienced another pulmonary embolism, but the Recovery Filter ultimately fractured, with multiple struts moving to her heart and pulmonary arteries, and Mrs. Tinlin subsequently underwent several surgical procedures. Although Mrs. Tinlin’s complication with the Recovery Filter is unfortunate, Bard is entitled to summary judgment on the following bases:

- Warnings-Based Claims (Counts II and VII): The plaintiffs’ claims fail under Wisconsin law¹ because of insufficient evidence that any “inadequate warning” caused the plaintiffs’ alleged injuries. Mrs. Tinlin’s doctor, Joshua Riebe, testified that he does not read Instructions for Use routinely and he has a general practice not to review letters from manufacturers. Moreover, he did not offer any testimony about whether different or additional information would have changed his decision to use the Recovery Filter for Mrs. Tinlin. (Indeed, Dr. Riebe did not have control over which filters his hospital stocked, and he did not identify any other filter as being available to implant in Mrs. Tinlin).
- Misrepresentation-Based Claims (Counts VIII, XII, XIII, and XIV): The plaintiffs’ claims fail because there is no evidence that either Mrs. Tinlin or Dr. Riebe relied on any alleged Bard misrepresentation or omission of material fact.
- Design-Based Claims (Counts III and IV): The plaintiffs’ strict liability and negligent design claims fail because the plaintiffs have no admissible evidence of a *reasonable* alternative design to the retrievable Recovery Filter.
- Loss of Consortium (Count XV): Mr. Tinlin’s loss of consortium claim is derivative of his wife’s claims. Thus, if the Court grants summary judgment on all of Mrs. Tinlin’s claims discussed above, then summary judgment also will be warranted on Mr. Tinlin’s loss of consortium claim because all of Mrs. Tinlin’s claims either will have been withdrawn or resolved on summary judgment.
- Future Damages: Drs. Muehrcke and Hurst have opined that Mrs. Tinlin may experience future complications because of her treatment with the

¹ The parties have stipulated that Wisconsin substantive law governs the plaintiffs’ claims.

Recovery Filter (e.g., cardiac arrhythmias, cardiac failure, recurrent diaphragm hernias, hemoptysis, pneumothorax, and death) that will require medical monitoring and other intervention for the rest of Mrs. Tinlin's life (e.g., semi-annual CT scans, procedures to remove the filter struts, and yearly appointments with physicians in multiple specialties). But Drs. Muehrcke and Hurst testified that they cannot quantify the risk of these future complications. As such, summary judgment on these claims for future damages is warranted.

II. Undisputed Facts.

On May 7, 2005, Dr. Joshua Riebe placed a Bard Recovery Filter in Debra Tinlin. (SOF ¶ 1.) Before receiving a Recovery Filter, Mrs. Tinlin had never heard of IVC filters. (*Id.* ¶ 2.) Mrs. Tinlin was asked during her deposition whether she was provided any written information regarding the filter, and she responded, "Not that I remember." (*Id.* ¶ 3.) Mrs. Tinlin has never spoken with anyone at Bard. (*Id.* ¶ 4.)

Dr. Riebe believed that Mrs. Tinlin was an appropriate candidate for a retrievable filter. (*Id.* ¶ 5.) In Dr. Riebe's practice, when determining whether to place a permanent versus a retrievable filter, he often puts something permanent in "extremely elderly patients that are probably going to outlive any potential complications," but "[a]s the patients are younger, it's often nice to put in something retrievable in the event that their current disease state can be treated with whatever's available, and you never know when other treatments become available and are invented." (*Id.* ¶ 6.) For Mrs. Tinlin, Dr. Riebe thought that using a retrievable filter gave him more options for the future. (*Id.* ¶ 7.)

Dr. Riebe did not routinely read Instructions for Use from medical device manufacturers, and he does not recall ever seeing the Instructions for Use for the Recovery Filter (*Id.* ¶¶ 8-9.) Moreover, Dr. Riebe cannot recall whether he ever met with a Bard sales representative generally or between 2004 and 2005 specifically. (*Id.* ¶ 10.) Likewise, the Bard sales representative for Dr. Riebe's hospital in 2004 and 2005, Timothy Fischer, does not remember Dr. Riebe. (*Id.* ¶ 19.) Similarly, Dr. Riebe does not

1 recall seeing any marketing material concerning IVC filters generally, or the Recovery
2 Filter brochure specifically. (*Id.* ¶ 11.) Likewise, Mr. Fischer does not remember ever
3 providing Dr. Riebe with Recovery Filter pamphlets or brochures. (*Id.* ¶ 20.) Finally,
4 Dr. Riebe cannot recall having attended any meetings where doctors spoke on behalf of
5 Bard about IVC filters. (*Id.* ¶ 12.)

6 Dr. Riebe does not recall ever receiving a “Dear Doctor” letter from Bard, he
7 receives “stacks and stacks” of mail at his facility, and he generally throws letters from
8 companies in the trash. (*Id.* ¶ 13.) Dr. Riebe’s regular practice is to not read Dear Doctor
9 letters from manufacturers, and he has no reason to believe that he ever would have read
10 Dear Doctor letters from Bard if he received them. (*Id.* ¶ 14.)

11 There is no evidence in the record that Dr. Riebe had any filter other than the
12 Recovery Filter available for use with Mrs. Tinlin, and Dr. Riebe believes that Mrs. Tinlin
13 needed to have an IVC filter placed. (*Id.* ¶¶ 15-16.) Dr. Riebe was not involved in the
14 decision-making process about which brands of IVC filters his hospital stocked, and he
15 believes that the hospital itself was the purchaser of the filters. (*Id.* ¶ 17.) He also does
16 not know whether anyone in his clinic negotiated with the hospital concerning which
17 products to stock. (*Id.* ¶ 18.) In short, there is no evidence in the record that Dr. Riebe
18 would have forgone use of the Recovery Filter for Mrs. Tinlin if Bard had provided him
19 with different or additional information (*Id.* ¶ 15.)

20 Dr. Robert McMeeking is the plaintiffs’ design expert. Dr. McMeeking has opined
21 that several features should have been incorporated into the Recovery Filter that “would
22 have helped to mitigate or eliminate the failures I have identified that occurred in
23 Mrs. Tinlin’s filter. . . : caudal anchors, penetration limiters, two-tier design, and a better
24 (smoother and rounded) chamfer at the mouth of the ‘cap’ on the filter.” (*Id.* ¶ 21.)
25 Dr. McMeeking has also identified several other permanent-only filters as “alternative
26 filters” to the Recovery Filter, including the Simon Nitinol Filter, the Greenfield Filter,
27 and the Bird’s Nest Filter. (*Id.* ¶ 22.)
28

1 Dr. Derek Muehrcke is the plaintiffs' cardiothoracic surgery expert. Dr. Muehrcke
 2 has opined that Mrs. Tinlin should have an attempt to remove all of her intrapulmonary
 3 fragments because of the future risks of bleeding, hemoptysis, pneumothorax, and death.
 4 (*Id.* ¶ 23.) But he cannot quantify the risk of these events for Mrs. Tinlin. (*Id.* ¶ 24.)
 5 Dr. Muehrcke has opined that Mrs. Tinlin should have the Recovery Filter removed
 6 because of the risk of future complications with the filter; and if a percutaneous attempt
 7 fails, then he would consider open (surgical) removal of the filter. (*Id.* ¶ 25.) He thinks
 8 that the risk of additional complications related to the filter itself is 40% at 5.5 years, and
 9 he refused to offer an opinion about whether the filter could be percutaneously retrieved.
 10 (*Id.* ¶ 26.) Dr. Muehrcke has opined that Mrs. Tinlin should have yearly cardiology EKGs
 11 and follow up to monitor her heart rhythm and cardiac function because of the risks of
 12 arrhythmias, cardiac failure, and endocarditis. (*Id.* ¶ 27.) But he cannot quantify the risk
 13 of these events for Mrs. Tinlin. (*Id.* ¶ 28.) Dr. Muehrcke has opined that Mrs. Tinlin
 14 should have yearly follow up with a cardiac surgeon to monitor her diaphragm hernia. (*Id.*
 15 ¶ 29.) But he thinks that the risk of recurrent or additional hernias is about 5%. (*Id.* ¶ 30.)
 16 Finally, Dr. Muehrcke has opined that Mrs. Tinlin should have semi-annual surveillance
 17 from a pulmonologist to monitor her shortness of breath from tracheomalacia and
 18 diaphragm injuries. (*Id.* ¶ 31.) But he did not perform a differential diagnosis concerning
 19 Mrs. Tinlin's shortness of breath (*Id.* ¶ 32), and Mrs. Tinlin's morbid obesity could cause
 20 shortness of breath. (*See id.* ¶ 33.)

21 Dr. Darren Hurst is the plaintiffs' interventional radiology expert. Dr. Hurst has
 22 opined that the filter fragments in Mrs. Tinlin's pulmonary arteries can cause
 23 complications like pneumothorax/collapse of the lung, abscess, and hemorrhage into the
 24 lung; and that Mrs. Tinlin will require lung resection to remove the filter struts if they
 25 become symptomatic. (*Id.* ¶ 34.) But he does not know what the risk is that these events
 26 will occur for Mrs. Tinlin. (*Id.* ¶ 35.) Dr. Hurst has opined that Mrs. Tinlin has
 27 experienced chronic cough and exacerbation of her asthma because of treatment with the
 28

1 Recovery Filter. (*Id.* ¶ 36.) But he cannot determine whether these issues are related to
 2 the filter or to Mrs. Tinlin’s preexisting medical conditions. (*Id.* ¶ 37.)

3 **III. Summary Judgment Standard.**

4 Summary judgment is appropriate when “there is no genuine dispute as to any
 5 material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P.
 6 56(a). “A moving party without the ultimate burden of persuasion at trial . . . has both the
 7 initial burden of production and the ultimate burden of persuasion on a motion for
 8 summary judgment.” *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102
 9 (9th Cir. 2000). “In order to carry its burden of production, the moving party must either
 10 produce evidence negating an essential element of the nonmoving party’s claim or defense
 11 or show that the nonmoving party does not have enough evidence of an essential element
 12 to carry its ultimate burden of persuasion at trial.” *Id.* “If . . . a moving party carries its
 13 burden of production, the nonmoving party must produce evidence to support its claim or
 14 defense.” *Id.* at 1130-31 (internal citations omitted).

15 **IV. Argument and Citation of Authority.**

16 **A. Plaintiffs’ warnings-based claims (Counts II and VII) fail as a matter of**
 17 **law because the plaintiffs have failed to present any evidence that an**
 18 **inadequate warning proximately caused Mrs. Tinlin’s injuries.**

19 In *In re Zimmer, NexGen Knee Implant Products Liability Litigation*, 884 F.3d 746
 20 (7th Cir. 2018), the Seventh Circuit recently analyzed whether the Wisconsin Supreme
 21 Court would adopt the learned intermediary doctrine. As the court discussed, the weight
 22 of authority in Wisconsin² strongly suggests that it would. Indeed, the only Wisconsin

23 ² *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273 at *20 (E.D. Wis. May
 24 12, 1999) (applying Wisconsin law, holding that under the learned-intermediary doctrine,
 25 “the manufacturer must warn the physician . . . and not the patient directly”); *Menges v.*
 26 *Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law)
 27 (“under the Learned Intermediary Doctrine, manufacturers of prescription medical
 28 products have a duty only to warn physicians, rather than patients, of the risks associated
 with the use of the product”); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963
 (E.D. Wis. 1981), *amended*, 532 F. Supp. 211 (E.D. Wis. 1981). Further, a Wisconsin
 state trial court has followed this rule and recognized that “courts of numerous other
 jurisdictions almost universally hold that in the case of prescription drugs, a
 manufacturer’s provision of proper warnings to a prescribing physician will satisfy the

1 court to decline application of the learned intermediary doctrine incorrectly noted that
 2 “Wisconsin does not apply the learned intermediary doctrine,” and offered no analysis
 3 about the issue. *Id.* at 751 (citing *Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL
 4 695817 (E.D. Wis. Feb. 26, 2013)). The Seventh Circuit reasoned that at least 48 states’
 5 highest courts or intermediate appellate courts have applied or favorably cited the learned
 6 intermediary doctrine and that the rationale “applies even more forcefully in cases
 7 involving surgical implants” because patients cannot obtain and implant such devices
 8 without the intervention and training of a physician. *Id.* at 751-52. The Seventh Circuit
 9 concluded, “[i]n short, there is good reason to think that given the opportunity, the
 10 Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt
 11 the learned-intermediary doctrine for use in defective-warning cases like this one
 12 involving a surgical implant. We predict that the state high court would do so.” *Id.* at 752.

13 Given the great weight of authority, this Court should find that the learned
 14 intermediary doctrine applies under Wisconsin law. Thus, in this case, Bard’s duty to
 15 warn about the risks of the Recovery Filter ran to Dr. Riebe, not to Mrs. Tinlin. And the
 16 plaintiffs can present no evidence from which a reasonable inference can be drawn that an
 17 “adequate warning” would have altered Dr. Riebe’s decision to use a Recovery Filter for
 18 Mrs. Tinlin:³

- 19 • Dr. Riebe does not recall ever seeing the Recover Filter IFU, and he does
 20 not routinely read IFUs. (SOF ¶¶ 8-9.) Thus, no reasonable inference can be
 21 drawn that Dr. Riebe would have read an IFU that contained an “adequate
 22 warning” and would have changed his decision to use the Recovery Filter
 23 for Mrs. Tinlin as a result.

24 manufacturer’s duty to warn since the patient cannot obtain the drug except through the
 25 physician.” *Straub v. Berg*, Nos. 00-CV-2100, 00-CV-0117, 2003 WL 26468454 at *6
 (Wis. Cir. Jan. 6, 2003) (citation omitted).

26 ³ See Wis. Stat. § 895.047 (1)(e) (requiring a plaintiff to prove that “the defective
 27 condition was a cause” of her injuries); *Kessel ex rel. Swenson v. Stansfield Vending, Inc.*,
 28 714 N.W.2d 206, 211-12 (Wis. Ct. App. 2006) (a plaintiff claiming negligent failure to
 warn must prove “a causal connection between the defendant’s breach of the duty of care
 and the plaintiff’s injury”).

- Dr. Riebe does not recall receiving any Dear Doctor letters from Bard; his practice is to throw Dear Doctor letters in the trash; and he has no reason to think that he ever would have read any Dear Doctor letter that Bard sent him. (*Id.* ¶¶ 13-14.) Thus, no reasonable inference can be drawn that Dr. Riebe would have read a Dear Doctor letter that contained an “adequate warning” and that he would have changed his decision to use the Recovery Filter for Mrs. Tinlin as a result.
- Regardless of the avenue that an “adequate warning” could have reached Dr. Riebe, even after being questioned about the information that the plaintiffs claim should have been provided to him, Dr. Riebe never testified or suggested that the information would have changed his decision to use the Recovery Filter for Mrs. Tinlin. (*Id.* ¶ 15.)
- Finally, Dr. Riebe testified that Mrs. Tinlin needed treatment with an IVC filter, and that Mrs. Tinlin was an appropriate candidate for a retrievable filter, but he never testified or suggested that any filter other than the Recovery Filter was available for use. (*Id.* ¶¶ 5, 7, 15.) And, he was not involved in the decision-making process about which filters his hospital stocked. (*Id.* ¶ 17.) Thus, no reasonable inference can be drawn that Dr. Riebe could have used a different filter for Mrs. Tinlin regardless of what warning Bard provided.

For these reasons, summary judgment on the plaintiffs’ failure-to-warn claims (Counts II and VII) is warranted.

B. Plaintiffs’ negligent and fraudulent misrepresentation/concealment claims (Counts VIII, XII, XIII) and claim for violation of Wisconsin law (Count XIV) fail as a matter of law because the plaintiffs cannot prove reliance or causation.

Plaintiffs’ misrepresentation and fraud claims require evidence of reliance or causation. *See Kohler Co. v. Kopietzki*, No. 13-cv-1170, 2016 WL 1048036, at *6 (E.D.

1 Wis. Mar. 11, 2016) (reliance is an element of fraudulent misrepresentation); *Consol.*
 2 *Papers, Inc. v. Dorr-Oliver, Inc.*, 451 N.W.2d 456, 459 (Wis. Ct. App. 1989) (reliance is
 3 an element of negligent misrepresentation); *Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023,
 4 1030 (E.D. Wis. 1998) (reliance is an element of fraudulent concealment); *Valente v.*
 5 *Sofamor, S.N.C.*, 48 F. Supp. 2d 862, 874 (E.D. Wis. 1999) (claim under Wisconsin
 6 Statute § 100.18 fails because no causal connection between defendant's alleged conduct
 7 and any pecuniary loss suffered by the plaintiffs).

8 The plaintiffs have no evidence showing that Mrs. Tinlin or Dr. Riebe relied on any
 9 representations by Bard or that Bard's public statements caused Mrs. Tinlin's alleged
 10 injuries. Mrs. Tinlin admits that she was not provided with any written information about
 11 the Recovery Filter and that she has never spoken with anyone at Bard. (SOF ¶¶ 3-4.) In
 12 fact, before being treated with the Recovery Filter, Mrs. Tinlin had never heard of IVC
 13 filters. (*Id.* ¶ 2.) Dr. Riebe does not recall that he ever met with any Bard sales
 14 representative nor does Bard's sales representative recall meeting with Dr. Riebe (*id.*
 15 ¶¶ 10, 19); Dr. Riebe does not recall seeing any marketing material about the Recovery
 16 Filter nor does Bard's sales representative recall providing him with an marketing material
 17 (*id.* ¶¶ 11, 20); finally, Dr. Riebe does not recall having attended any meetings where
 18 doctors spoke on behalf of Bard about IVC filters (*id.* ¶ 12). Because the plaintiffs have
 19 no evidence that Mrs. Tinlin or Dr. Riebe relied on any alleged representations made by
 20 Bard, or that Bard's alleged concealment of information caused the plaintiffs' alleged
 21 injuries, the plaintiffs' fraud and misrepresentation claims (Counts VIII, XII, XIII, and
 22 XIV) fail as a matter of law.

23 **C. The plaintiffs' design-based claims (Counts III and IV) fail as a matter of**
 24 **law because the plaintiffs have no admissible evidence of a reasonable**
 25 **alternative design.**

26 The plaintiffs' negligent and strict liability design defect claims require evidence of
 27 a reasonable alternative design the omission of which rendered the product not reasonably
 28 safe. Wis. Stat. § 895.047(1)(a) ("A product is defective in design if the foreseeable risks

of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe.”); *Below v. Yokohama Tire Corp.*, No. 15-CV-529-WMC, 2017 WL 679153, at *3 (W.D. Wis. Feb. 21, 2017) (“in the negligence context, the reasonableness of a product’s design turns essentially on whether the seller could have come up with a less dangerous design.” (quotations and citations omitted)). Moreover, the plaintiffs must prove their design claims by expert opinion in a case, such as this, that involves complex medical and scientific issues. *See Johnson v. Mylan, Inc.*, 107 F. Supp. 3d 967, 974-75 (E.D. Wis. 2015) (finding that expert testimony is required to prove their design defect in a case that involves scientific and medical issues that are beyond the layperson’s common knowledge).

The plaintiffs’ design expert, Dr. McMeeking, offers numerous alternative designs to the Recovery Filter that are specific to Mrs. Tinlin’s case. He claims that the Recovery Filter should have incorporated “caudal anchors, penetration limiters, two-tier design, and a better (smoother and rounded) chamfer at the mouth of the ‘cap’ on the filter.” (SOF ¶ 21.) He also identifies several other permanent-only filters as “alternative filters” to the Recovery Filter, including the Simon Nitinol Filter (in violation of the Court’s prior *Daubert* Order (Doc. 10051)), the Greenfield Filter, and the Bird’s Nest Filter. (SOF ¶ 22.)

Bard has moved to exclude these opinions of Dr. McMeeking, and, if the Court grants Bard’s motion, the plaintiffs will not be able to satisfy the alternative design requirements of their strict liability and negligent design claims as they relate to Mrs. Tinlin’s specific filter, and summary judgment will be warranted.

Moreover, any identification of the Simon Nitinol Filter (or any other permanent-only filter, such as the Greenfield Filter or the Bird’s Nest Filter), should fail as a matter of law. In *Oden v. Boston Sci. Corp.*, CV 18-0334 (SJF)(SIL), 2018 U.S. Dist. LEXIS 102639, at **12-13 (E.D.N.Y. June 4, 2018), the Eastern District of New York found that an IVC filter that was designed to be removable was not a reasonable alternative for an

1 IVC filter that was designed to stay in the IVC permanently. The converse is true in the
 2 Bard IVC Filter MDL—an IVC filter that is designed to stay in the IVC permanently is
 3 not a reasonable alternative design for an IVC filter that is designed to be removable.
 4 Although the Court was unpersuaded by this argument in *Hyde* (see Rule 50 Or. (Doc.
 5 12805), at 6), the facts of *Tinlin* warrant a different result because unlike the implanting
 6 physician in *Hyde*, Dr. Riebe specifically testified that Mrs. Tinlin was an appropriate
 7 candidate for a retrievable filter (SOF ¶ 5), that he uses permanent filters for “extremely
 8 elderly patients” but uses retrievable filters in younger patients (*id.* ¶ 6), and that he
 9 thought that using a retrievable filter for Mrs. Tinlin gave him more options for the future
 10 (*id.* ¶ 7). Thus, unlike in *Hyde*, where the implanting physician’s dissimilar testimony
 11 may have created a question of fact as to whether a permanent filter could be a reasonable
 12 alternative design in that case given the circumstances of Ms. Hyde’s medical history, in
 13 *Tinlin*, the facts demonstrate that a permanent-only filter was not a *reasonable* alternative
 14 design to the retrievable filter that Dr. Riebe wanted to use for Mrs. Tinlin. See *Hosford v.*
 15 *BRK Brands, Inc.*, 223 So.3d 199 (Ala. 2016) (affirming judgment as a matter of law that
 16 “dual-sensor smoke alarms” are not reasonable alternative designs to “ionization smoke
 17 alarms” and noting that “a design for a different, albeit similar, product, even if it serves
 18 the same purpose” is not a reasonable alternative design); *Caterpillar, Inc. v. Shears*, 911
 19 S.W.2d 379 (Tex. 1995) (finding as a matter of law that a loader with a permanently
 20 installed rollover protective structure was not a reasonable alternative design for a loader
 21 with a removable rollover protective structure because the permanent product could not
 22 fulfill the multi-purpose roll of the loader with a removable structure); *Niedner v. Ortho-*
 23 *McNeil Pharm., Inc.*, 58 N.E.3d 1080, 1087 (Mass. Ct. App. 2016) (finding as a matter of
 24 law that oral contraceptives are not a reasonable alternative design to a patch
 25 contraceptive even though both products are hormonal contraceptives that prevent
 26 pregnancy); *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760 (Tex. App. 2009) (finding
 27 as a matter of law that Wyeth’s predecessor product (Premarin), which had the same
 28 essential purpose as Wyeth’s allegedly defective product (Prempro)—namely, to treat

menopausal symptoms—was not a reasonable alternative design to Prempro because the two medications were different products and because Prempro could be useful in populations of patients that Premarin was not). These cases all illustrate that an alternative design that removes a key benefit of the allegedly defective product cannot serve as a *reasonable* alternative design.⁴ Here, too, by eliminating the ability of the Recovery Filter to be removed—the key benefit of the filter that allows it to serve a “multi-purpose role” and be “useful in populations of patients” that a permanent-only filter is not—the plaintiffs’ proposed alternative designs cannot be *reasonable* alternative designs as a matter of law.

Finally, as a matter of law, a defective product cannot be a reasonable alternative design. *Tunnell v. Ford Motor Co.*, 385 F. Supp. 2d 582, 586 (W.D. Va. 2005) (noting that “the necessity of establishing that a proposed alternative design would satisfy the risk-benefit analysis is a matter of common sense. . . . Without such evidence, it is impossible to determine whether the proposed alternative design would truly cure a product of its alleged defect, or instead merely substitute one defect for another. One need not refer to the Third Restatement, academic commentary, or interpretive decisions to understand this basic point.”). Thus, the plaintiffs’ identification of other manufacturers’ filters (like Cook’s Filters that Dr. McMeeking has opined are defective) and plaintiffs’ identification of design features that Bard incorporated in later generations of its IVC filters (all of which Dr. McMeeking has opined are defective), cannot satisfy the plaintiffs’ burden of proving a *reasonable* alternative design to the Recovery Filter.

For each of these reasons, summary judgment is warranted on the plaintiffs’ design claims (Counts III and IV).

⁴ This logic holds true for the *Oden* court’s understanding that the plaintiff in that case needed a permanent filter and the plaintiff offered as a reasonable alternative design a filter that was designed to be retrieved. Because the proposed alternative design removed a key benefit (permanency) that was needed given the medical circumstances presented in that case, the alternative design was not reasonable as a matter of law.

D. If the Court grants summary judgment on all of the grounds raised above, then Mr. Tinlin’s loss of consortium claim (Count XV) also fails as a matter of law.

One spouse’s loss of consortium claim is derivative of the other spouse’s claims for personal injury. *See Kottka v. PPG Indus., Inc.*, 388 N.W.2d 160, 170 (Wis. 1986) (“The claim for a loss of consortium is derivative, in the sense that it does not arise unless the other spouse has sustained a personal injury.”) (citing additional cases). Thus, because Mr. Tinlin’s claim for loss of consortium is derivative of Mrs. Tinlin’s claims for injury, if the Court finds that Mrs. Tinlin’s claims fail as a matter of law, then Mr. Tinlin’s claim for loss of consortium (Count XV) must likewise fail.

E. Many of the plaintiffs’ claims for future damages have an insufficient evidentiary basis to proceed to trial.

Future injuries and medical care must be established by a medical *probability*, not a mere possibility. *See Bleyer v. Gross*, 120 N.W.2d 156, 160 (Wis. 1963) (finding that “an expert opinion expressed in terms of a ‘mere possibility’ is insufficient to sustain a finding”) (citations omitted); *McGarrity v. Welch Plumbing Co.*, 312 N.W.2d 37, 44-45 (Wis. 1981) (“the court of appeals correctly held that an expert opinion expressed in terms of possibility or conjecture is insufficient”); *Weber v. White*, 681 N.W.2d 137, 143 (Wis. 2004) (“The law does not require mathematical certainty to determine future health care expenses. As long as the decision is based on probability and not possibility, the court can make such an award.”) (citing *Bleyer*).

Dr. Muehrcke could not opine that Mrs. Tinlin *probably* would have any of the following future complications as a result of her treatment with the Recovery Filter: bleeding, hemoptysis, pneumothorax, death, additional complications with the filter, arrhythmias, cardiac failure, endocarditis, or additional hernias. (SOF ¶¶ 24, 26, 28, 30.) Moreover, Dr. Muehrcke did not perform a differential diagnosis concerning Mrs. Tinlin’s shortness of breath to rule out preexisting morbid obesity as the cause. (*Id.* ¶ 32.) As such, the monitoring and medical intervention costs that Dr. Muehrcke recommends for

these issues should not be compensable (including removing the filter fragments, possible surgery, semi-annual CT scans, yearly EKGs, yearly follow-up with a cardiologist, and yearly follow up with a pulmonologist, yearly follow up with a cardiac surgeon).

Likewise, Dr. Hurst could not opine that Mrs. Tinlin *probably* would have any of the following future complications as a result of her treatment with the Recovery Filter: pneumothorax/collapse of the lung, abscess, or hemorrhage into the lung. (SOF ¶¶ 34-35.) Moreover, Dr. Hurst cannot determine whether Mrs. Tinlin's chronic cough and exacerbation of her asthma were related to the filter or her preexisting medical conditions. (*Id.* ¶ 37.) Accordingly, the monitoring and medical intervention costs that Dr. Hurst recommends for these issues should not be compensable (including life-long CT scans and possible lung resection).

V. Conclusion.

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Summary Judgment.

RESPECTFULLY SUBMITTED this 1st day of February, 2019.

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